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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,274	11/06/2006	Cyril Delattre	10404-041.00	3441

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,274	DELATTRE ET AL.	
	Examiner	Art Unit	
	Betty Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-9,11-22 and 25-33* is/are pending in the application.

5a) Of the above claim(s) *26-32* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-9,11-22,25 and 33* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 23 August 2011 in which claims 1, 25 and 33 were amended and claim 10 was canceled. The amendments have been thoroughly reviewed and entered.

The previous object of Claim 25 in the Office Action dated 23 February 2011 is withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. §102(e) and 35 U.S.C. § 103(a) are maintained.

Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims 1-9, 11-22, 25 and 33 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 5, 7, 11-14, 17, 25 and 33 are under 35 U.S.C. 102(e) as being anticipated by Schleifer et al (2004/0119013, filed 23 December 2002).

Regarding Claim 1, Schleifer teaches a work device comprising a sample holder (e.g. 43, ¶ 38) and a substrate (e.g. 41, ¶ 38-45) that is non-wetting for the liquid of interest (¶ 45) and a plurality of work zones (40) on the active surface surrounded by a border wherein the border is non-wetting for the liquid of interest (¶ 66). Schleifer teaches that liquid introduced into the sample holder, the liquid of interest covers the work zone and that the borders have geometry such that when liquid of interest is extracted, the liquid remains within the work zone (¶ 81). Schleifer further teaches the borders are formed in relief (¶ 69) and such that when sample is delivered to the substrate using a pipette or syringe (¶ 81) thereby providing the means for introducing and extracting liquid as claimed and as defined by the instant specification (page 29, lines 17-24).

> The means for introducing the liquid of interest into the box may comprise any appropriate means known to a person skilled in the art for injecting a liquid into a box, particularly those used in the field of on-chip laboratories and Microsystems. These introduction means may be selected, for example, from a syringe, a pipette, a micropipette, an injection pump, etc.

Schleifer further and specifically teaches the work zone is non-wetting for the liquid of interest (¶ 45) as reproduced below:

> Suitable substrates may derive from naturally occurring materials, naturally occurring materials that have been synthetically modified, or synthetic materials.

> Generally, the substrates are electrically conductive, e.g., made entirely of an electrically conductive material or coated or layered with an electrically conductive material, etc. In many embodiments, at least a portion of the substrate is hydrophobic, where it may be inherently hydrophobic or may be made to be hydrophobic, e.g., by a hydrophobic agent, chemical manipulation, etc. By " hydrophobic" it is meant that at least a portion of a surface of substrate is substantially if not completely unwettable and substantially if not completely liquid repellant for the sample contacted thereto, even if the sample is not an aqueous solution. For example, in the case of an oily-based sample, it should therefore correspondingly be a lipophobic surface. In certain embodiments, at least a portion of a subject substrate is hydrophilic, where the material of the subject substrate may be inherently hydrophilic or be made hydrophilic, e.g., by a hydrophilic agent, chemical manipulation, etc. By "hydrophilic" it is meant that at least a portion of a surface of a subject substrate is easily wettable for the type of sample contacted thereto, even if the sample is not an aqueous solution. In certain embodiments, a substrate surface may have one or more areas that are hydrophobic and one or more areas that are hydrophilic.***(emphasis added)***

Regarding Claim 2, Schleifer teaches the work zone is on the same plane as the active surface i.e. the interior area is defined by the fluid retaining structure and substrate surface (¶ 50)

Regarding Claim 5, Schleifer teaches the work zone is used as a MALDI senor (Abstract).

Regarding Claim 7, Schleifer teaches the work zone is a zone for detecting a biological species in a sample (¶ 76-77).

Regarding Claim 11, Schleifer teaches the substrate is made of an organic polymer, plastic, glass, silicon (¶ 46).

Regarding Claim 12, Schleifer teaches the substrate is made of polycarbonate (¶ 46).

Regarding Claim 13, Schleifer teaches the substrate is made of aluminum (¶ 46).

Regarding Claim 14, Schleifer teaches the borders have a shape selected from e.g. square rectangle, oval (¶ 52).

Regarding Claim 17, Schleifer teaches the borders are formed by molding (¶ 69). However, it is noted that the instantly claimed method of making the borders does not define the borders over a prior art method using a different method.

Regarding Claim 25, Schleifer teaches the device of Claim 1 wherein the substrate comprises nucleic acids, proteins or cells (¶ 77).

Regarding Claim 33, Schleifer teaches a work device comprising a sample holder (e.g. 43, ¶ 38) and a substrate (e.g. 41, ¶ 38-45) that is non-wetting for the liquid of interest (¶ 45) and a plurality of work zones (40) on the active surface surrounded by a border wherein the border is non-wetting for the liquid of interest (¶ 66). Schleifer teaches that liquid introduced into the sample holder, the liquid of interest covers the work zone and that the borders have geometry such that when liquid of interest is extracted, the liquid remains within the work zone (¶ 81). Schleifer further teaches the borders are formed in relief (¶ 69) and have a height of 5-20 μm (¶ 57) and such that when sample is delivered to the substrate using a pipette or syringe (¶ 81) thereby providing the means for introducing and extracting liquid as claimed and as define by the instant specification. Schleifer teaches the work zone is non-wetting for the liquid of interest (¶ 45).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 8-9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schleifer et al (2004/0119013, filed 23 December 2002) in view of Brennan (U.S. Patent No. 6,210,894, issued 3 April 2001).

Regarding Claims 1-3, 8-9 and 16, Schleifer teaches that a variety of analytes are analyzed within the work zones (¶ 76-77) but does not teach that the zones are functionalized with probes for analyte capture and analysis.

However, Brennan teaches a similar device comprising a substrate in the work box comprising an active surface that is non-wetting (6) a plurality of work zones on the active surface, each surrounded by a border that is non-wetting wherein the borders are not touching and have no common edge (Fig. 3) wherein the opening are arranged for introducing fluid to cover the surface of the substrate (flooded) and the borders have a geometry such that when the liquid of interest is extracted, a drop of liquid remains in contact with the work zone (Column 7, lines 37-59 and Column 8, lines 45-57). Brennan further teaches the zone is functionalized with an oligonucleotide probe to interacting with a target (Example 4, Column 9) and wherein the borders are wetting for the liquid of interest as illustrated by the droplet contact of the border (Fig.3).

Brennan teaches that functionalizing the regions with known sequences provides for unambiguous determination of the target sequence (Column 3, lines 9-19).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the zones of Schleifer by functionalizing the zones with capture oligonucleotides as taught by Brennan. The artisan would have been motivated to do with a reasonable expectation of success based on the teaching of Brennan. The artisan would have been further motivated to do so for the benefit of unambiguous determination of the target sequence as desired in the art (Brennan, Column 3, lines 9-19).

6. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schleifer et al (2004/0119013, filed 23 December 2002) in view of Heller (U.S. Patent No. 6,017,696, issued 25 January 2000) and Ikeda et al (U.S. Patent No. 5,582,697, issued 10 December 1996).

Regarding Claim 4, Schleifer teaches the substrate is a metal and/or electrically conductive (¶ 45) but does not teach an electrochemical microcell.
However, Heller teaches these elements wherein substrates comprise a metal (Column 15, lines 28-30) and further teaches that it is advantageous to construct an electrochemical microcell in order to extract specific molecules from a sample (Column 12 lines 35-54). Heller further teaches numerous advantages provided by the electrodes including stringency control, rapid transport target molecules and rapid

removal of non-specific materials (Column 24, 19-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan by constructing an electrochemical microcell in order to extract specific molecules from a sample as desired in the art (Heller, Column 12, lines 35-45.

Regarding Claim 6, Heller teaches the advantages of using electrode work zones as discussed above regarding Claim 4. While Heller does not specifically teach that the electrodes actuate, Ikeda teaches a similar biosensor wherein the sample detection occurs via electrode actuator (Example 3). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the actuation of Ikeda to the device of Schleifer and/or Heller. One of ordinary skill in the art would have been motivated to do so based on its well-known use in the art as taught by Ikeda.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schleifer et al (2004/0119013, filed 23 December 2002)

Regarding Claim 15, Schleifer teaches the borders "may assume a variety of different shapes... from simple to complex" (¶ 52) and further teaches the width or diameter may change from top to bottom (¶ 58) but the reference is silent regarding specific shapes in cross section.

However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the fluid retaining structures of Schleifer with any shape in cross section e.g. triangular based on the dimensional changes suggested

by the reference. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the structures to obtain those instantly claimed because the ordinary artisan would have expected the work zones to function equally regardless the shape based on the variety of possible configurations taught by Schleifer.

> The courts have stated that claimed dimensions of a known device do not distinguish over the prior art device when the claimed device would not perform differently from the prior art device. In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

8. Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schleifer et al (2004/0119013, filed 23 December 2002) in view of Brennan (U.S. Patent No. 6,210,894, issued 3 April 2001) and Yuen (U.S. Patent Application Publication No. 2002/0168624, published 14 November 2002).

Regarding Claims 18-22, Schleifer teaches the device wherein the sample is delivered to the substrate using any convenient protocol e.g. pipette or syringe (¶ 81) but does not teach a pump for injecting the liquid.

However, pumps for injecting liquids into reaction devices were well known in the art at the time the invention was made as taught by Brennan. Brennan also teaches the

similar device comprising inlet (1) and outlet ports (2) wherein the inlet is connect to the reagent manifold (Fig. 7). Brennan further teaches the assembly is enclosed in a glove box which can be evacuated or purged with argon e.g. positive displacement or flushing (Column 8, lines 58-64) which clearly suggests a pump and/or vacuum is attached to evacuate or purge the chamber. While the reference does not specifically teach a pump and vacuum these tools were well known in the art for evacuating and purging hybridization chambers as taught by Yuen (¶ 35, 42). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well-known pump and vacuum to the device of Schleifer and/or Brennan. One of ordinary skill in the art would have been motivated to do so based on the well-known use of these elements as taught by Yuen (¶ 35, 42).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-22, 25 and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/576,345 (2007/0207055). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to substrates with capture zones and surrounding borders. The claim sets merely differ in the arrangement of limitations within the claim sets. For example, independent Claim 1 of the instant claims defines the substrate in a work box while dependent Claim 33 of the '345 set defines this element. Therefore the claim sets define inventions that are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. On page 9 of the Response, Applicant asserts that Schleifer does not teach that "the substrate is wettable specifically for the sample in contact therewith (i.e. the 'sample of interest')".

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., wettable for the sample) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The instant claims are drawn to in part:

- a substrate (S) comprising an active surface that is substantially ***non-wetting*** for said liquid of interest contained in said box,
- a plurality of distinct work zones (Zt) formed on said active surface and each surrounded by a border (b) formed on said active surface that is substantially non-wetting for the liquid of interest, the borders not touching one another and having no common edge, and the work zones (Zt) being substantially ***non-wetting*** for said liquid of interest,***(emphasis added)***

As reproduced above, Schleifer specifically teaches a substrate that is non-wetting for the sample of interest. Therefore it is maintained that Schleifer anticipates the invention as claimed.

Applicant further argues that Schleifer teaches an embodiment without retaining structures and therefore cannot anticipate the invention as claimed.

The argument has been considered but is not found persuasive. Even if the reference provides an embodiment without retaining structures, that does not alter the fact that the reference clearly, specifically and repeatedly teaches embodiments having retaining structures (¶ 49-71).

It is maintained that Schleifer anticipates the invention as claimed.

Regarding Claim 33, Applicant asserts that Schleifer fails to teach borders that are structures in relief having a height of 5-20 microns. Applicant acknowledges that Schleifer teaches a thickness of the retaining structures but asserts that this is not at teaching of border height as claimed.

Schleifer teaches border structures are fluid retaining structures for retaining volumes of 0.1-10 microliters (¶ 56) and to allow laser illumination of the fluid volume at appropriate angle (¶ 57). To provide the illumination and fluid retaining property the structures have a thickness of 5-100 microns (¶ 57). Applicant appears to be asserting that the retaining structure "thickness" differs from border "height" as recited in the claim. It is unclear how the thickness of Schleifer differs from the claimed height.

Regarding the rejections under 35 U.S.C. 103, Applicant asserts that neither Brennan, Heller nor Ikeda cure the deficiencies of Schleifer. The argument is not sufficient to overcome the rejection because Schleifer is not deemed deficient.

Regarding the rejection under non-statutory double patenting, Applicant has not provided any arguments to traverse the rejection.

On page 12 of the response, Applicant requests a phone call to discuss step necessary for placing the application in condition for allowance. An attempt was made to contact Mr. Bailey, but he was unavailable for discussion.

Conclusion

12. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Forman whose telephone number is (571)272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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